

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION**

JEWEL FRAZIER and FRANK FRAZIER,
JR.,

Plaintiffs,

v.

COOK INCORPORATED; COOK
MEDICAL LLC (f/k/a COOK MEDICAL
INCORPORATED); and WILLIAM COOK
EUROPE ApS,

Defendants.

Case No.: 4:20-cv-1192

JURY TRIAL DEMANDED

COMPLAINT

COME NOW Plaintiffs Jewel Frazier and Frank Frazier, Jr., and for their cause of action against Defendants Cook Incorporated, Cook Medical LLC (f/k/a Cook Medical Incorporated), and William Cook Europe ApS, allege the following:

PARTIES

1. Plaintiff Jewel Frazier is an adult and a citizen of the State of Illinois.
2. Plaintiff Frank Frazier, Jr. is an adult and citizen of the State of Illinois. At all relevant times, he has been married to Plaintiff Jewel Frazier.
3. Defendant Cook Incorporated is an Indiana Corporation with its principal place of business located in the State of Indiana. At all relevant times, Defendant Cook Incorporated, and/or its predecessors in interest, were engaged in the business of research, designing, testing, formulating, inspecting, labeling, manufacturing, packaging, marketing, distributing, producing, processing, promoting and selling inferior vena cava (“IVC”) filter medical devices in St. Louis and throughout Missouri and the United States.

4. Defendant Cook Medical, LLC, formerly known as Cook Medical Incorporated, is an Indiana Limited Liability Company organized under the laws of Indiana, with its principal place of business located in the State of Indiana. Defendant Cook Medical LLC's members are corporations with principal-places-of-business located in Indiana or otherwise reside in and are citizens of Indiana. Accordingly, Cook Medical LLC is a citizen of Indiana for purposes of determining diversity under 28 U.S.C. § 1332. At all relevant times, Defendant Cook Medical, LLC and/or its predecessors in interest, were engaged in the business of research, designing, testing, formulating, inspecting, labeling, manufacturing, packaging, marketing, distributing, producing, processing, promoting and selling inferior vena cava ("IVC") filter medical devices in St. Louis and throughout Missouri and the United States.

5. Defendant William Cook Europe ApS is a company based in Bjaeverskov, Denmark. At all relevant times, Defendant William Cook Europe ApS and/or its predecessors in interest, were engaged in the business of research, designing, testing, formulating, inspecting, labeling, manufacturing, packaging, marketing, distributing, producing, processing, promoting and selling inferior vena cava ("IVC") filter medical devices in St. Louis and throughout Missouri and the United States.

6. Hereinafter, each of the above Defendants shall be collectively referred to as "Defendants" or "Cook." At all times alleged herein, Defendants include and included any and all parent companies, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

7. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessors in interest, and joint venturer of each of the remaining Defendants herein and was at all

times operating and acting with the purpose and scope of said agency, service, employment, partnership, and joint venture.

8. At all times relevant, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce in Missouri and throughout the United States, either directly or indirectly through third parties, subsidiaries or related entities, unsafe medical devices known as the Gunther Tulip Mreye, Gunther Tulip Vena Cava Filter, Cook Celect Vena Cava Filter, and Cook Celect Platinum Vena Cava Filter, hereinafter collectively referred to as “Cook IVC Filter(s)” or “Cook’s IVC Filter(s).”

9. This action arises out of injuries sustained by Plaintiffs caused by a Cook IVC Filter that was implanted in Plaintiff Jewel Frazier. In particular, the Cook IVC Filter Plaintiff received and at issue is a Cook Celect Vena Cava Filter (“Celect IVC Filter”).

JURISDICTION AND VENUE

10. Subject matter jurisdiction is proper in this Court pursuant to 28 U.S.C. § 1332(a)(1) because the Plaintiffs and Defendants are citizens of different states and the amount in controversy exceeds \$75,000.00, exclusive of interest and costs.

11. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 as a substantial part of the events or omissions giving rise to this claim occurred in this District, including the fact that Plaintiff Jewel Frazier was implanted with the Cook IVC Filter at issue in this District.

12. The Court has personal jurisdiction because, at all pertinent times, Defendants have conducted and continue to conduct continuous and systematic business in the State of Missouri and this District, have purposefully injected their products, including Cook IVC Filters, into the stream of commerce to be sold in Missouri and this District, and have taken actions such that they should anticipate being sued in the State of Missouri and this District. Further, Defendants have transacted business in the State of Missouri and this District that has given rise to this specific cause of action, and

have committed torts in whole or in part in the State of Missouri and this District, including torts giving rise to this action. This includes the marketing and selling of the Cook IVC Filter at issue.

13. Plaintiffs bring this action to recover for injuries caused by unreasonably dangerous and defective Cook IVC Filter that was surgically implanted in Plaintiff Jewel Frazier.

GENERAL FACTUAL ALLEGATIONS

Background

14. At all pertinent times, Defendants designed, researched, developed, manufactured, tested, marketed, advertised, promoted, distributed, and sold medical devices known as Cook IVC Filters (i.e., Gunther Tulip Mreye, Gunther Tulip Vena Cava Filter, Cook Celect Vena Cava Filter, and Cook Celect Platinum Vena Cava Filter), that are sold and marketed as temporary and/or retrievable devices to prevent, among other things, recurrent pulmonary embolism via placement in the vena cava.

15. Defendants sought Food and Drug Administration (“FDA”) approval to market their Celect IVC Filter and/or its components under Section 510(k) of the Medical Device Amendment.

16. Defendants obtained Food and Drug Administration (“FDA”) approval to market their Celect IVC Filter device and/or its components under section 510(k) of the Medical Device Amendment.

17. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the said device.

18. An IVC Filter, like the Celect IVC Filter, is a device designed to filter blood clots (called “thrombi”) that would otherwise travel from the lower portions of the body to the heart and lungs. IVC filters may be designed to be implanted, either temporarily or permanently, within the vena cava.

19. The inferior vena cava is a vein that returns blood to the heart from the lower portion of the body. In certain people, and for various reasons, thrombi travel from vessels in the legs and pelvis, through the vena cava into the lungs. Often these thrombi develop in the deep leg veins. The thrombi are called “deep vein thrombosis” or DVT. Once the thrombi reach the lungs they are considered “pulmonary emboli” or PE.

20. An IVC Filter, like the Celect IVC Filter, is designed to prevent thromboembolic events by filtering or preventing blood clots/thrombi from traveling to the heart and/or lungs.

21. The Celect IVC Filter was released for sale in the United States in 2007, is currently sold and marketed as a temporary retrievable filter, and is based on the Gunther Tulip Vena Cava filter and the Gunther Tulip MREYE filter.

22. The Celect IVC Filter has four (4) anchoring struts for fixation and eight (8) independent secondary struts intended to improve self-centering and clot trapping.

23. At all pertinent times, Celect IVC Filters were widely advertised and promoted by Defendants as a safe and effective treatment for the filtering of blood clots and the prevention of pulmonary embolism via placement in the vena cava.

24. At all pertinent times, Defendants knew its Celect IVC Filter was defective and knew that the defects were attributable to the design’s failure to withstand the normal anatomical and physiological loading cycles exerted in vivo.

25. At all pertinent times, Defendants failed to disclose to physicians and patients that its Celect IVC Filter was subject to breakage and migration or the appropriate degree of risk of perforation to the vena cava wall.

26. At all pertinent times, failed to disclose to physicians, patients, or Plaintiff that its Celect IVC filter could cause blood clots and/or that the device was not effective in preventing pulmonary emboli.

27. At all pertinent times, the Defendants continued to promote their Celect IVC Filter as safe and effective even though the clinical trials that had been performed were not adequate to support long or short-term efficacy.

28. The Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with their Celect IVC Filter, as aforesaid.

29. Defendants' Celect IVC Filters are constructed of conichrome.

30. Defendants specifically advertise the conichrome construction of the filter as a frame which "reduces the risk of fracture."

31. The failures of Celect IVC Filters are attributable, in part, to the fact that Cook IVC Filters suffer from a design defect that cause them to be unable to withstand the normal anatomical and physiological loading cycles exerted in vivo.

32. At all pertinent times, Defendants failed to provide sufficient warnings and instructions of the dangers and adverse effects caused by implantation of Celect IVC Filters, including, but not limited to the design's failure to withstand the normal anatomical and physiological loading cycles exerted in vivo.

33. Celect IVC Filters were designed, manufactured, distributed, sold and/or supplied by the Defendants, and were marketed while defective due to the inadequate warnings, instructions, labeling, and/or inadequate testing in light of Defendants' knowledge of the products failure and serious adverse events.

Plaintiff Jewel Frazier's Celect IVC Filter

34. Plaintiff Jewel Frazier was surgically implanted with the Celect IVC Filter at issue on January 25, 2011 at St. Louis University Hospital, located in St. Louis, Missouri.

35. On or about November 15, 2019, Ms. Frazier sought treatment for lower back pain. Diagnostic testing performed in conjunction with that treatment revealed for the first-time problems

with her filter, including fractured struts and a strut embolized to her right middle lobe. Plaintiff's injuries and damages caused by Defendants' tortious conduct at issue in this case were not sustained and capable of ascertainment until this date at the earliest.

36. On or about December 13, 2019, Plaintiff Jewel Frazier underwent surgery at Barnes Jewish Hospital to remove the Celect IVC Filter at issue.

37. Plaintiff was injured by her Celect IVC Filter fracturing and migrating as a direct and proximate result of the device's unreasonably dangerous and defective design, and Defendants' negligence in designing, marketing, labeling, and selling the product. Plaintiff was caused to suffer severe and personal injuries, which are permanent and lasting in nature, including, but not limited to, physical pain, mental anguish, diminished enjoyment of life, expenses for medical treatment, as well other personal and pecuniary harm.

COUNT I - STRICT PRODUCTS LIABILITY-FAILURE TO WARN

38. Plaintiffs incorporate by reference each of the preceding paragraphs as fully set forth herein.

39. Celect IVC Filters were defective and unreasonably dangerous when they left the possession of the Defendants in that they contained warnings insufficient to alert consumers, including Plaintiffs, of the dangerous risks associated with the subject product, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death.

40. Information provided by Defendants to the medical community and to consumers concerning the safety and efficacy of its Celect IVC Filters did not accurately reflect the serious and potentially fatal adverse events Plaintiff and product users could suffer

41. At all pertinent times, Celect IVC Filters were dangerous and presented a substantial danger to patients who were implanted with Celect IVC Filters, and these risks and dangers were known

or knowable at the times of distribution and implantation in Plaintiff. Ordinary consumers would not have recognized the potential risks and dangers the Celect IVC Filters posed to patients, because their use was specifically promoted to improve health of such patients.

42. Had adequate warnings and instructions been provided, Plaintiff Jewel Frazier would not have been implanted with a Celect IVC Filter, and would not have been at risk of the harmful injuries described herein. The Defendants failed to provide warnings of such risks and dangers to Plaintiff and her medical providers as described herein. Neither Plaintiff, nor her physicians knew, nor could they have learned through the exercise of reasonable care, the risks of serious injury and/or death associated with and/or caused by Cooks' Celect IVC Filters.

43. Defendants knew or had knowledge that the warnings that were given failed to properly warn of the increased risks of serious injury and/or death associated with and/or caused by Celect IVC Filters.

44. Plaintiff, individually and through her implanting physicians, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

45. Defendants had a continuing duty to warn Plaintiffs and her physicians of the dangers associated with Celect IVC Filters.

46. Safer alternatives were available that were effective and without risks posed by Celect IVC Filters.

47. As a direct and proximate result of her Celect IVC Filter's defects, as described herein, Plaintiff Jewel Frazier was injured as aforesaid. Plaintiff Jewel Frazier has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

WHEREFORE, Plaintiffs pray for judgment against Defendants, each of them, in an amount in excess of \$75,000.00, for costs expended herein, and for such further and other relief as the Court deems just and proper.

COUNT II - STRICT PRODUCTS LIABILITY-DESIGN DEFECT

48. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

49. Defendants have a duty to provide adequate warnings and instructions for their products including their Celect IVC Filters, to use reasonable care to design a product that is not unreasonably dangerous to users.

50. At all pertinent times, Defendants designed, tested, manufactured, packaged, labeled, marketed, distributed, promoted and sold Celect IVC Filters, placing the devices into the stream of commerce.

51. At all pertinent times, Celect IVC Filters, were designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed by Defendants in a condition that was defective and unreasonably dangerous to consumers, including Plaintiff.

52. Celect IVC Filters are defective in their design and/or formulation in that they are not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with their design and formulation.

53. Celect IVC Filters were expected to reach, and did reach, users and/or consumers including Plaintiffs, without substantial change in the defective and unreasonably dangerous condition in which they were manufactured and sold.

54. Plaintiff Jewel Frazier's physicians implanted her Celect IVC Filter via the Instructions for Use and in a foreseeable manner as normally intended, recommended, promoted, and marketed by

the Defendants. Plaintiff received and utilized her Celect IVC Filter in a foreseeable manner as normally intended recommend, promoted, and marketed by the Defendants.

55. Celect IVC Filters were and are unreasonably dangerous in that, as designed, failed to perform safely when used by ordinary consumers, including Plaintiff, including when the filters were used as intended and in a reasonably foreseeable manner.

56. Celect IVC Filters were and are unreasonably dangerous and defective in design or formulation for their intended use in that, when they left the hands of the manufacturers and/or supplier, they posed a risk of serious vascular and/or other serious injury which could have been reduced or avoided , inter alia, by the adoption of a feasible alternative design. There were safer alternative designs for like products.

57. Celect IVC Filters were insufficiently tested and caused harmful adverse events that outweighed any potential utility.

58. Celect IVC Filters, as manufactured and supplied, were defective due to its no longer being substantially equivalent to its predicate device with regard to safety and effectiveness.

59. Celect IVC Filters as manufactured and supplied by the Defendants are and were defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of injuries from use and acquired additional knowledge and information confirming the defective and dangerous nature of its Celect IVC Filters, Defendants failed to provide adequate warnings to the medical community and the consumers, to whom Defendants were directly marketing and advertising; and further, Defendants continued to affirmatively promote their Celect IVC Filters as safe and effective and as safe and effective as their predicate device.

60. As a direct and proximate result of her Celect IVC Filter's defects, as described herein, Plaintiff Jewel Frazier was injured as aforesaid. Plaintiff Jewel Frazier has suffered and will continue

to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

WHEREFORE, Plaintiffs pray for judgment against Defendants, each of them, in an amount in excess of \$75,000.00, for costs expended herein, and for such further and other relief as the Court deems just and proper.

COUNT III - NEGLIGENCE

61. Plaintiffs incorporate by referenced each of the preceding paragraphs as if fully set forth herein.

62. At all pertinent times, Defendants were in the business of designing, developing, manufacturing, marketing and selling sophisticated medical devices, including Celect IVC Filters.

63. At all pertinent times, Defendants were under a duty to act reasonably to design, develop, manufacture, market and sell a product that did not present a risk of harm or injury to the Plaintiff and to those people receiving their Celect IVC Filters.

64. At the time of the manufacture and sale Plaintiff Jewel Frazier's Celect IVC Filter, Defendants knew, or reasonably should have known, that Celect IVC Filters:

- a. were designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device, as aforesaid;
- b. were designed and manufactured so as to present an unreasonable risk of migration of the device and/or portions of the device, as aforesaid;
- c. were designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body; and/or
- d. were designed and manufactured so as to present an unreasonable risk of perforation and damage to the caval wall.

65. Despite the aforementioned duty of the part of the Defendants, they committed one or more breaches of their duty of reasonable care and were negligent in:

- a. unreasonably and carelessly failing to properly warn of the dangers and risks of harm associated with Celect IVC Filters, specifically its incidents fracture, migration, perforation and other failure;
- b. unreasonably and carelessly manufacturing a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body;
- c. unreasonably and carelessly designed a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body; and/or
- d. unreasonably and carelessly designed a product that presented a risk of harm to the Plaintiffs and others similarly situated in that it was prone to fail.

66. As a direct and proximate result of Defendants' negligent acts as described above, Plaintiff Jewel Frazier was injured as aforesaid. Plaintiff Jewel Frazier has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

WHEREFORE, Plaintiffs pray for judgment against Defendants, each of them, in an amount in excess of \$75,000.00, for costs expended herein, and for such further and other relief as the Court deems just and proper.

COUNT IV - NEGLIGENCE PER SE

67. Plaintiffs incorporate by referenced each of the preceding paragraphs as if fully set forth herein.

68. At all pertinent times, Defendants had an obligation not to violate the law, including the Federal Food, Drug and Cosmetic Act and the applicable regulations, in the manufacture, design, testing, production, processing, assembling, inspection, research, promotion, advertising, distribution, marketing, promotion, labeling, packaging, preparation for use, consulting, sale, warning and post-sale warning and other communications of the risks and dangers of Celect IVC Filters.

69. By reason of its conduct as alleged herein, Defendants violated provisions of statutes and regulations, including but not limited to, the following:

- a. Defendants violated the Federal Food, Drug and Cosmetic Act, 21, U.S.C. §§ 331 and 352, by misbranding Celect IVC Filters;
- b. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321 in making statements and/or representations via word, design, device or any combination thereof failing to reveal material facts with respect to the consequences that may result from the use of Celect IVC Filters to which the labeling and advertising relates;
- c. Defendants violated the 21 C.F.R. §1.21 in misleading the consumers and patients by concealing material facts in light of representations made regarding safety and efficacy of its Celect IVC Filters;
- d. Defendants violated the 21 C.F.R. §801 in mislabeling its Celect IVC Filters as to safety and effectiveness of its products and by failing to update its label to reflect post-marketing evidence that Celect IVC Filters were associated with an increased risk of injuries due to tilting, fracture, migration and perforation;
- e. Defendants violated the 21 C.F.R. §803 by not maintaining accurate medical device reports regarding adverse events of tilting, fracture, migration and perforation and/or misreporting these adverse events maintained via the medical device reporting system;

- f. Defendants violated the 21 C.F.R. §807 by failing to notify the FDA and/or the consuming public when its Celect IVC Filters were no longer substantially equivalent with regard to safety and efficacy with regard to post-marketing adverse events and safety signals; and
- g. Defendants violated the 21 C.F.R. §820 by failing to maintain adequate quality systems regulation including, but not limited to, instituting effective corrective and preventative actions.

70. As a direct and proximate result of Defendants' negligent acts as described above, Plaintiff Jewel Frazier was injured as aforesaid. Plaintiff Jewel Frazier has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

WHEREFORE, Plaintiffs pray for judgment against Defendants, each of them, in an amount in excess of \$75,000.00, for costs expended herein, and for such further and other relief as the Court deems just and proper.

COUNT V - BREACH OF EXPRESS WARRANTY

71. Plaintiffs incorporate by referenced each of the preceding paragraphs as if fully set forth herein.

72. At all pertinent times, Defendants were merchants of goods of the kind including medical devices and vena cava filters (i.e., Celect IVC Filters).

73. At the time and place of sale, distribution and supply of Plaintiff's Celect IVC Filter, the Defendants expressly represented and warranted in their marketing materials, both written and orally, and in the IFUs, that the Celect IVC Filter was safe, well-tolerated, efficacious, and fit for its intended purpose and was of marketable quality, that it would not produce any unwarned-of dangerous side effects, and that it was adequately tested.

74. At the time of Plaintiff's purchase from Defendants, the Celect IVC Filter at issue was not in a merchantable condition and Defendants breached their expressed warranties, in that the filter:

- a. was designed in such a manner so as to be prone to a unreasonably high incident of fracture, perforation of vessels and organs, and/or migration;
- b. was designed in such a manner so as to result in a unreasonably high incident of injury to the organs of its purchaser; and
- c. was manufactured in such a manner so that the exterior surface of the Celect Filters were inadequately, improperly and inappropriately designed causing the device to weaken and fail.

75. As a direct and proximate result of the aforementioned breach of warranties, Plaintiff Jewel Frazier was injured as aforesaid. Plaintiff Jewel Frazier has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

WHEREFORE, Plaintiffs pray for judgment against Defendants, each of them, in an amount in excess of \$75,000.00, for costs expended herein, and for such further and other relief as the Court deems just and proper.

COUNT VI - BREACH OF IMPLIED WARRANTY

76. Plaintiffs incorporate by referenced each of the preceding paragraphs as if fully set forth herein.

77. At all pertinent times, Defendants manufactured, distributed, advertised, promoted, and sold Celect IVC Filters.

78. At all pertinent times, Defendants intended its Celect IVC Filters be used in the manner that Plaintiffs in fact used her Celect IVC Filter.

79. Defendants impliedly warranted that Plaintiff's Celect IVC Filter was of merchantable quality, safe and fit for the use for which the Defendants intended it and for which Plaintiff in fact used it.

80. Defendants breached their implied warranties as follows:

- a. Defendants failed to provide the warning or instruction and/or an adequate warning or instruction which a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that its Celect IVC Filters would cause harm;
- b. Defendants manufactured and/or sold their Celect IVC Filters and said filters did not conform to representations made by the Defendants when they left the Defendants' control;
- c. Defendants manufactured and/or sold their Celect IVC Filters which were more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, and the foreseeable risks associated with the Celect Filters' design or formulation exceeded the benefits associated with that design. These defects existed at the time the products left the Defendants' control; and
- d. Defendants manufactured and/or sold their Celect IVC Filters when they deviated in a material way from the design specifications, formulas or performance standards or from otherwise identical units manufactured to the same design specifications, formulas, or performance standards, and these defects existed at the time the products left the Defendants' control.

81. Further, Defendants' marketing of their Celect IVC Filters was false and/or misleading.

82. Plaintiff Jewel Frazier, through her attending physicians, relied on these representations in determining which IVC filter to use for implantation in the Plaintiff.

83. Defendants' filters were unfit and unsafe for use by users as they posed an unreasonable and extreme risk of injury to persons using said products, and accordingly Defendants breached their expressed warranties and the implied warranties associated with the product.

84. The foregoing warranty breaches were a substantial factor in causing Plaintiffs' injuries and damages as alleged.

85. As a direct and proximate result of the aforementioned breach of warranties, Plaintiff Jewel Frazier was injured as aforesaid. Plaintiff Jewel Frazier has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

WHEREFORE, Plaintiffs pray for judgment against Defendants, each of them, in an amount in excess of \$75,000.00, for costs expended herein, and for such further and other relief as the Court deems just and proper.

COUNT VII - LOSS OF CONSORTIUM

86. Plaintiffs incorporate by referenced each of the preceding paragraphs as if fully set forth herein.

87. At all pertinent times, Plaintiff Frank Frazier, Jr. is and has been the husband of Plaintiff Jewel Frazier, and has suffered his own injuries and losses as a direct and proximate result of Plaintiff Jewel Frazier's injuries as described above. These losses included, but not limited to, economic injuries, as well as loss of his spouse's support, companionship, services, society, love and affection.

WHEREFORE, Plaintiffs pray for judgment against Defendants, each of them, in an amount in excess of \$75,000.00, for costs expended herein, and for such further and other relief as the Court deems just and proper.

COUNT VIII -PUNITIVE DAMAGES

88. Plaintiffs incorporate by referenced each of the preceding paragraphs as if fully set forth herein.

89. At all times material hereto, Defendants knew or should have known that their Celect IVC Filters were inherently dangerous with respect to the risk of tilt, fracture, migration and/or perforation.

90. At all times material hereto, Defendants attempted to misrepresent and did knowingly misrepresent facts concerning the safety of their Celect IVC Filters.

91. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiffs' physicians, concerning the safety of their Celect IVC Filters. The Defendants' conduct was willful, wanton, and undertaken with a conscious indifference to the consequences that consumers of their product faced, including Plaintiff.

92. At all times material hereto, Defendants knew and recklessly disregarded the fact that their Celect IVC Filters have an unreasonably high rate of tilt, fracture, migration and/or perforation.

93. Notwithstanding the foregoing, Defendants continued to market their Celect IVC Filters aggressively to consumers, including Plaintiffs, without disclosing the aforesaid side effects.

94. Defendants knew of their Celect IVC Filters' lack of warnings regarding the risk of fracture, migration, and/or perforation, but intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and sell their Filters without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiffs, in conscious disregard of the foreseeable harm caused by Celect's IVC Filters.

95. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiff's physicians of necessary information to enable them to weigh the true risks of using Celect IVC Filters against their benefits.

96. As a direct and proximate result of Defendants' willful, wanton, careless, reckless, conscious, and deliberate disregard for the safety and rights of consumers, including Plaintiff Jewel Frazier, Plaintiff and other consumers have suffered and will continue to suffer severe and permanent physical and emotional injuries, as described with particularity, above.

97. Defendants' aforesaid conduct was committed with knowing, conscious, careless, reckless, willful, wanton, and deliberate disregard for the safety and rights of consumers including Plaintiffs, thereby entitling Plaintiffs to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiffs pray for judgment against Defendants, each of them, in an amount in excess of \$75,000.00, for costs expended herein, and for such further and other relief as the Court deems just and proper.

Respectfully submitted,

By: /s/ Michael S. Kruse
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